K053593

510 (k) Summary

General Information Establishment

JUL - 6 2006

Applicant: DIAGNOSTIC DEVICES, INC.Inc.
Address: 8935 NW 27th street, Miami, FL 33172. U.S.A.
Registration Number: 3004622211
Contact Person: Rick Admani Abulhaj
Director of Finance and Operation
TEL: 1-800-2432636
FAX: 1-305-6205220
Data submitted: December 21, 2005

Device

Proprietary /Trade Name: Prodigy Blood Glucose Test System
Common Name: Blood Glucose Test System
Classification Name: SYSTEM, TEST BLOOD GLUCOSE, Class II
Regulation sections: 21 CFR § 862.13485, Glucose Test System
21 CFR § 862.1660, Quality Control Material, assayed and Unassayed.
Classification: Class II (Glucose Test System)
Class I -reserved (Quality Control Material)
Product code: NBW, CGA (Glucose Test System)
JJX (Quality Control Material)
Panel: 75 (Clinical Chemistry)-Glucose Test system and Quality Control Material

Safety and Effective Information

Predicate Device:
Claim of Substantial Equivalence (SE) is made to TaiDoc Technology Corporation. K042005, Achtung TD-4207/ Clever Chek TD-4209/ Clever Chek TD-4222 Glucose Test Systems.

Indications for Use:

The *Prodigy* Blood Glucose Test System is intended for use in the quantitative measurement of glucose in whole blood taken from the finger. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and are not intended for use on neonates.

Device Description:

The Prodigy glucose test system consists of a meter and test strips. The system utilizes an electrochemical method-based meter and dry reagent biosensor (test strips) for blood glucose testing. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measurement of glucose in fresh whole blood and control solutions.

Safety and Effectiveness, comparison to predicate device:

The results of clinical and non-clinical testing indicate that the new device is as safe and effective as the predicate.

Substantial Equivalence Chart:

Similarities		
Item	**New Device: Prodigy**	**Predicate K042005**
Enzyme	Glucose oxidase	Glucose oxidase
Test range	20-600 mg/dL	20-600 mg/dL
Test strip calibration	Code strip	Code strip
Sample volume	1.8-2.5 uL	1.8-2.5 uL
Test time	10 sec.	10 sec.
Operating condition and humidity range	10 - 40°C 10 – 90 % R.H.	10 - 40°C 10 – 90 % R.H.
Storage/Transportation condition	-20 - 70°C 5 – 95 % R.H.	-20 - 70°C 5 – 95 % R.H.
Difference		
Item	**New Device: Prodigy**	**Predicate K042005**
Size	88mm X 62mm X 22mm	80mm X 60mm X 20mm
Weight	26.5 g	48.79 g

Conclusion

After analyzing clinical and non-clinical testing data, it is the conclusion of Diagnostic Devices, Inc.,Inc. that the prodigy blood Glucose Test system is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Diagnostic Devices Inc.
c/o Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm& Associates
PO Box 7007
Deerfield IL 60015

JUL - 6 2006

Re: k053593
Trade/Device Name: Prodigy Blood Glucose Test System
Regulation Number: 21 CFR§ 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: June 12, 2006
Received: June 14, 2006

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

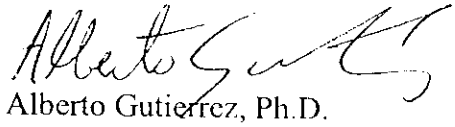
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K053593

Device Name: *Prodigy Blood Glucose Test System*

Indications For Use:

The *Prodigy Blood Glucose Test System* is intended to be used for the quantitative measurement of glucose in capillary whole blood from the fingertip. It is intended for use by people with diabetes mellitus at home (Over –the-Counter) as an aid in monitoring the effectiveness of diabetes control program. The Prodigy blood glucose test system can also be used at clinical sites by nurses or professional people to test patient's glucose level in whole blood. It is not intended for the diagnosis of or screening for diabetes mellitus, and not intended for use on neonates.

The Prodigy meter is to be used with the Prodigy Blood Glucose Test Strip, and the Prodigy Glucose Control Solutions.

Prescription Use __X____ AND/OR Over-The-Counter Use ____X_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
...vision Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K053593